



CITY OF CHICAGO
ECONOMIC DISCLOSURE STATEMENT and AFFIDAVIT
Related to Contract/Amendment/Solicitation
EDS # 150542

SECTION I -- GENERAL INFORMATION

A. Legal name of the Disclosing Party submitting the EDS:

Shift Medical, Ltd.

Enter d/b/a if applicable:

SHIFT

The Disclosing Party submitting this EDS is:

the Applicant

B. Business address of the Disclosing Party:

750 N. Orleans
Suite 101
Chicago, IL 60654
United States

C. Telephone:

847-275-7386

Fax:

312-277-5252

D. Name of contact person:

Dr. Ari Michael Levy

F. Brief description of contract, transaction or other undertaking (referred to below as the "Matter") to which this EDS pertains:

EMERGENCY REQUEST FOR COVID-19 RAPID TEST KITS

Which City agency or department is requesting this EDS?

DEPT OF HEALTH

Specification Number

1201877

Contract (PO) Number

127815

Revision Number

Release Number

User Department Project Number

SECTION II -- DISCLOSURE OF OWNERSHIP INTERESTS

A. NATURE OF THE DISCLOSING PARTY

1. Indicate the nature of the Disclosing Party:

Other

Please specify the nature of your enterprise.

An Illinois Medical Corporation

Is the Disclosing Party incorporated or organized in the State of Illinois?

Yes

B. DISCLOSING PARTY IS A LEGAL ENTITY:

1.a.1 Does the Disclosing Party have any directors?

No

1.a.3 List below the full names and titles of all executive officers and all directors, if any, of the entity. Do not include any directors who have no power to select the entity's officers.

Officer/Director: Dr. Ari Michael Levy
Title: President
Role: Officer

.....

2. Ownership Information

Please provide ownership information concerning each person or entity that holds, or is anticipated to hold (see next paragraph), a direct or indirect beneficial interest in excess of 7.5% of the Applicant. Examples of such an interest include shares in a corporation, partnership interest in a partnership or joint venture, interest of a member or manager in a limited liability company, or interest of a beneficiary of a trust, estate, or other similar entity. Note: Each legal entity below may be required to submit an EDS on its own behalf.

Please disclose present owners below. Please disclose anticipated owners in an attachment submitted through the "Additional Info" tab. "Anticipated owner" means an individual or entity in existence at the time application for City action is made, which is not an applicant or owner at such time, but which the applicant expects to assume a legal status, within six months of the time the City action occurs, that would render such individual or entity an applicant or owner if they had held such legal status at the time application was made.

- Dr. Ari Michael Levy - 100%

Owner Details

Name	Business Address
Dr. Ari Michael Levy	750 N. Orleans Suite 101 Chicago, IL 60654 United States

SECTION III -- INCOME OR COMPENSATION TO, OR OWNERSHIP BY, CITY ELECTED OFFICIALS

A. Has the Disclosing Party provided any income or compensation to any City elected official during the 12-month period preceding the date of this EDS?

No

B. Does the Disclosing Party reasonably expect to provide any income or compensation to any City elected official during the 12-month period following the date of this EDS?

No

D. Does any City elected official or, to the best of the Disclosing Party's knowledge after reasonable inquiry, any City elected official's spouse or domestic partner, have a financial interest (as defined in [Chapter 2-156 of the Municipal Code](#) ("MCC")) in the Disclosing Party?

No

SECTION IV -- DISCLOSURE OF SUBCONTRACTORS AND OTHER RETAINED PARTIES

The Disclosing Party must disclose the name and business address of each subcontractor, attorney, lobbyist (as defined in [MCC Chapter 2-156](#)), accountant, consultant and any other person or entity whom the Disclosing Party has retained or expects to retain in connection with the Matter, as well as the nature of the relationship, and the total amount of the fees paid or estimated to be paid. The Disclosing Party is not required to disclose employees who are paid solely through the Disclosing Party's regular payroll.

If the Disclosing Party is uncertain whether a disclosure is required under this Section, the Disclosing Party must either ask the City whether disclosure is required or make the disclosure.

1. Has the Disclosing Party retained or does it anticipate retaining any legal entities in connection with the Matter?

No

3. Has the Disclosing Party retained or does it anticipate retaining any persons in connection with the Matter?

No

SECTION V -- CERTIFICATIONS

A. COURT-ORDERED CHILD SUPPORT COMPLIANCE

Under [MCC Section 2-92-415](#), substantial owners of business entities that contract with the City must remain in compliance with their child support obligations throughout the contract's term.

Has any person who directly or indirectly owns 10% or more of the Disclosing Party been declared in arrearage of any child support obligations by any Illinois court of competent jurisdiction?

No

B. FURTHER CERTIFICATIONS

1. [This certification applies only if the Matter is a contract being handled by the City's Department of Procurement Services.] In the 5-year period preceding the date of this EDS, neither the Disclosing Party nor any [Affiliated Entity](#) has engaged, in connection with the performance of any public contract, the services of an integrity monitor, independent private sector inspector general, or integrity compliance consultant (i.e. an individual or entity with legal, auditing, investigative, or other similar skills, designated by a public agency to help the agency monitor the activity of specified agency vendors as well as help the vendors reform their business practices so they can be considered for agency contracts in the future, or continue with a contract in progress).

I certify the above to be true

2. The Disclosing Party and its Affiliated Entities are not delinquent in the payment of any fine, fee, tax or other source of indebtedness owed to the City of Chicago, including, but not limited to, water and sewer charges, license fees, parking tickets, property taxes and sales taxes, nor is the Disclosing Party delinquent in the payment of any tax administered by the Illinois Department of Revenue.

I certify the above to be true

3. The Disclosing Party and, if the Disclosing Party is a legal entity, all of those persons or entities identified in Section II(B)(1) of this EDS:

- a. are not presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from any transactions by any federal, state or local unit of government;
- b. have not, during the 5 years before the date of this EDS, been convicted of a criminal offense, adjudged guilty, or had a civil judgment rendered against them in connection with: obtaining, attempting to obtain, or performing a public (federal, state or local) transaction or contract under a public transaction; a violation of federal or state antitrust statutes; fraud; embezzlement; theft; forgery; bribery; falsification or destruction of records; making false statements; or receiving stolen property;
- c. are not presently indicted for, or criminally or civilly charged by, a governmental entity (federal, state or local) with committing any of the offenses set forth in subparagraph (b) above;

- d. have not, during the 5 years before the date of this EDS, had one or more public transactions (federal, state or local) terminated for cause or default; and
- e. have not, during the 5 years before the date of this EDS, been convicted, adjudged guilty, or found liable in a civil proceeding, or in any criminal or civil action, including actions concerning environmental violations, instituted by the City or by the federal government, any state, or any other unit of local government.

I certify the above to be true

4. The Disclosing Party understands and shall comply with the applicable requirements of MCC [Chapter 2-56 \(Inspector General\)](#) and [Chapter 2-156 \(Governmental Ethics\)](#).

I certify the above to be true

5. Neither the Disclosing Party, nor any [Contractor](#), nor any [Affiliated Entity](#) of either the Disclosing Party or any [Contractor](#), nor any [Agents](#) have, during the 5 years before the date of this EDS, or, with respect to a [Contractor](#), an [Affiliated Entity](#), or an [Affiliated Entity](#) of a [Contractor](#) during the 5 years before the date of such [Contractor's](#) or [Affiliated Entity's](#) contract or engagement in connection with the Matter:

- a. bribed or attempted to bribe, or been convicted or adjudged guilty of bribery or attempting to bribe, a public officer or employee of the City, the State of Illinois, or any agency of the federal government or of any state or local government in the United States of America, in that officer's or employee's official capacity;
- b. agreed or colluded with other bidders or prospective bidders, or been a party to any such agreement, or been convicted or adjudged guilty of agreement or collusion among bidders or prospective bidders, in restraint of freedom of competition by agreement to bid a fixed price or otherwise; or
- c. made an admission of such conduct described in subparagraph (a) or (b) above that is a matter of record, but have not been prosecuted for such conduct; or
- d. violated the provisions referenced in [MCC Subsection 2-92-320\(a\)\(4\)\(Contracts Requiring a Base Wage\)](#); [\(a\)\(5\)\(Debarment Regulations\)](#); or [\(a\)\(6\)\(Minimum Wage Ordinance\)](#).

I certify the above to be true

6. Neither the Disclosing Party, nor any [Affiliated Entity](#) or [Contractor](#), or any of their employees, officials, [agents](#) or partners, is barred from contracting with any unit of state or local government as a result of engaging in or being convicted of

- bid-rigging in violation of [720 ILCS 5/33E-3](#);
- bid-rotating in violation of [720 ILCS 5/33E-4](#); or

- any similar offense of any state or of the United States of America that contains the same elements as the offense of bid-rigging or bid-rotating.

I certify the above to be true

7. Neither the Disclosing Party nor any [Affiliated Entity](#) is listed on a Sanctions List maintained by the United States Department of Commerce, State, or Treasury, or any successor federal agency.

I certify the above to be true

8. [FOR APPLICANT ONLY]

- Neither the Applicant nor any "controlling person" [[see MCC Chapter 1-23, Article I](#) for applicability and defined terms] of the Applicant is currently indicted or charged with, or has admitted guilt of, or has ever been convicted of, or placed under supervision for, any criminal offense involving actual, attempted, or conspiracy to commit bribery, theft, fraud, forgery, perjury, dishonesty or deceit against an officer or employee of the City or any "sister agency" ; and
- the Applicant understands and acknowledges that compliance with Article I is a continuing requirement for doing business with the City.

NOTE: If [MCC Chapter 1-23, Article I](#) applies to the Applicant, that Article's permanent compliance timeframe supersedes 5-year compliance timeframes in this Section V.

I certify the above to be true

9. [FOR APPLICANT ONLY] The Applicant and its Affiliated Entities will not use, nor permit their subcontractors to use, any facility listed as having an active exclusion by the U.S. EPA on the [federal System for Award Management](#) ("SAM")

I certify the above to be true

10. [FOR APPLICANT ONLY] The Applicant will obtain from any contractors/subcontractors hired or to be hired in connection with the Matter certifications equal in form and substance to those in Certifications (2) and (9) above and will not, without the prior written consent of the City, use any such contractor/subcontractor that does not provide such certifications or that the Applicant has reason to believe has not provided or cannot provide truthful certifications.

I certify the above to be true

11. To the best of the Disclosing Party's knowledge after reasonable inquiry, the following is a complete list of all current employees of the Disclosing Party who

were, at any time during the 12-month period preceding the date of this EDS, an employee, or elected or appointed official, of the City of Chicago.

None

12. To the best of the Disclosing Party's knowledge after reasonable inquiry, the following is a complete list of all gifts that the Disclosing Party has given or caused to be given, at any time during the 12-month period preceding the execution date of this EDS, to an employee, or elected or appointed official, of the City of Chicago. For purposes of this statement, a "gift" does not include: (i) anything made generally available to City employees or to the general public, or (ii) food or drink provided in the course of official City business and having a retail value of less than \$25 per recipient, or (iii) a political contribution otherwise duly reported as required by law.

None

C. CERTIFICATION OF STATUS AS FINANCIAL INSTITUTION

The Disclosing Party certifies, as defined in [MCC Section 2-32-455\(b\)](#), the Disclosing Party

is not a "financial institution"

D. CERTIFICATION REGARDING FINANCIAL INTEREST IN CITY BUSINESS

Any words or terms defined in [MCC Chapter 2-156](#) have the same meanings if used in this Part D.

1. In accordance with [MCC Section 2-156-110](#): To the best of the Disclosing Party's knowledge after reasonable inquiry, does any official or employee of the City have a financial interest in his or her own name or in the name of any other person or entity in the Matter?

No

E. CERTIFICATION REGARDING SLAVERY ERA BUSINESS

If the Disclosing Party cannot make this verification, the Disclosing Party must disclose all required information in the space provided below or in an attachment in the "Additional Info" tab. Failure to comply with these disclosure requirements may make any contract entered into with the City in connection with the Matter voidable by the City.

The Disclosing Party verifies that the Disclosing Party has searched any and all records of the Disclosing Party and any and all predecessor entities regarding records of investments or profits from slavery or slaveholder insurance policies during the slavery era (including insurance policies issued to slaveholders that

provided coverage for damage to or injury or death of their slaves), and the Disclosing Party has found no such records.

I can make the above verification

SECTION VI -- CERTIFICATIONS FOR FEDERALLY FUNDED MATTERS

Is the Matter federally funded? For the purposes of this Section VI, tax credits allocated by the City and proceeds of debt obligations of the City are not federal funding.

No

SECTION VII - FURTHER ACKNOWLEDGMENTS AND CERTIFICATION

The Disclosing Party understands and agrees that:

- A. The certifications, disclosures, and acknowledgments contained in this EDS will become part of any contract or other agreement between the Applicant and the City in connection with the Matter, whether procurement, City assistance, or other City action, and are material inducements to the City's execution of any contract or taking other action with respect to the Matter. The Disclosing Party understands that it must comply with all statutes, ordinances, and regulations on which this EDS is based.
- B. The City's Governmental Ethics Ordinance, [MCC Chapter 2-156](#), imposes certain duties and obligations on persons or entities seeking City contracts, work, business, or transactions. The full text of this ordinance and a training program is available on line at www.cityofchicago.org/Ethics, and may also be obtained from the City's Board of Ethics, 740 N. Sedgwick St., Suite 500, Chicago, IL 60610, (312) 744-9660. The Disclosing Party must comply fully with this ordinance.

I acknowledge and consent to the above

The Disclosing Party understands and agrees that:

- C. If the City determines that any information provided in this EDS is false, incomplete or inaccurate, any contract or other agreement in connection with which it is submitted may be rescinded or be void or voidable, and the City may pursue any remedies under the contract or agreement (if not rescinded or void), at law, or in equity, including terminating the Disclosing Party's participation in the Matter and/or declining to allow the Disclosing Party to participate in other

City transactions. Remedies at law for a false statement of material fact may include incarceration and an award to the City of treble damages.

- D. It is the City's policy to make this document available to the public on its Internet site and/or upon request. Some or all of the information provided in, and appended to, this EDS may be made publicly available on the Internet, in response to a Freedom of Information Act request, or otherwise. By completing and signing this EDS, the Disclosing Party waives and releases any possible rights or claims which it may have against the City in connection with the public release of information contained in this EDS and also authorizes the City to verify the accuracy of any information submitted in this EDS.
- E. The information provided in this EDS must be kept current. In the event of changes, the Disclosing Party must supplement this EDS up to the time the City takes action on the Matter. If the Matter is a contract being handled by the City's Department of Procurement Services, the Disclosing Party must update this EDS as the contract requires. NOTE: With respect to Matters subject to MCC Article I of [Chapter 1-23](#) (imposing PERMANENT INELIGIBILITY for certain specified offenses), the information provided herein regarding eligibility must be kept current for a longer period, as required by [MCC Chapter 1-23](#) and [Section 2-154-020](#).

I acknowledge and consent to the above

APPENDIX A - FAMILIAL RELATIONSHIPS WITH ELECTED CITY OFFICIALS AND DEPARTMENT HEADS

This Appendix is to be completed only by (a) the Applicant, and (b) any legal entity which has a direct ownership interest in the Applicant exceeding 7.5%. It is not to be completed by any legal entity which has only an indirect ownership interest in the Applicant.

Under [MCC Section 2-154-015](#), the Disclosing Party must disclose whether such Disclosing Party or any "Applicable Party" or any Spouse or Domestic Partner thereof currently has a "familial relationship" with any elected city official or department head. A "familial relationship" exists if, as of the date this EDS is signed, the Disclosing Party or any "Applicable Party" or any Spouse or Domestic Partner thereof is related to the mayor, any alderman, the city clerk, the city treasurer or any city department head as spouse or domestic partner or as any of the following, whether by blood or adoption: parent, child, brother or sister, aunt or uncle, niece or nephew, grandparent, grandchild, father-in-law, mother-in-law, son-in-law, daughter-in-law, stepfather or stepmother, stepson or stepdaughter, stepbrother or stepsister or half-brother or half-sister.

"Applicable Party" means (1) all corporate officers of the Disclosing Party, if the Disclosing Party is a corporation; all partners of the Disclosing Party, if the

Disclosing Party is a general partnership; all general partners and limited partners of the Disclosing Party, if the Disclosing Party is a limited partnership; all managers, managing members and members of the Disclosing Party, if the Disclosing Party is a limited liability company; (2) all principal officers of the Disclosing Party; and (3) any person having more than a 7.5% ownership interest in the Disclosing Party. "Principal officers" means the president, chief operating officer, executive director, chief financial officer, treasurer or secretary of a legal entity or any person exercising similar authority.

Does the Disclosing Party or any "Applicable Party" or any Spouse or Domestic Partner thereof currently have a "familial relationship" with an elected city official or department head?

No

APPENDIX B - BUILDING CODE SCOFFLAW/PROBLEM LANDLORD CERTIFICATION

This Appendix is to be completed only by (a) the Applicant, and (b) any legal entity which has a direct ownership interest in the Applicant exceeding 7.5% (an "Owner"). It is not to be completed by any legal entity which has only an indirect ownership interest in the Applicant.

Pursuant to [MCC Section 2-154-010](#), is the Applicant or any Owner identified as a building code scofflaw or problem landlord pursuant to [MCC Section 2-92-416??](#)

No

APPENDIX C-PROHIBITION ON WAGE & SALARY HISTORY SCREENING

This Appendix is to be completed only by an Applicant that is completing this EDS as a "contractor" as defined in [MCC Section 2-92-385](#). That section, which should be consulted (www.amlegal.com), generally covers a party to any agreement pursuant to which they: (i) receive City of Chicago funds in consideration for services, work or goods provided (including for legal or other professional services), or (ii) pay the City money for a license, grant or concession allowing them to conduct a business on City premises.

On behalf of an Applicant that is a contractor pursuant to [MCC Section 2-92-385](#), I hereby certify that the Applicant is in compliance with [MCC Section 2-92-385\(b\)\(1\)](#) and (2), which prohibit: (i) screening job applicants based on their wage or salary history, or (ii) seeking job applicants' wage or salary history from current or former employers. I also certify that the Applicant has adopted a policy that includes those prohibitions.

This certification shall serve as the affidavit required by [MCC Section 2-92-385\(c\)\(1\)](#).

Yes

ADDITIONAL INFO

Please add any additional explanatory information here. If explanation is longer than 1000 characters, you may add an attachment below. Please note that your EDS, including all attachments, becomes available for public viewing upon contract award. Your attachments will be viewable "as is" without manual redaction by the City. You are responsible for redacting any non-public information from your documents before uploading.

11,000 of units Standard Q COVID-19 IgG/IgM Rapid Test

List of vendor attachments uploaded by City staff

None .

List of attachments uploaded by vendor

Standard Q COVID-19 IgG/IgM Rapid Test

CERTIFICATION

Under penalty of perjury, the person signing below: (1) warrants that he/she is authorized to execute this EDS, and Appendices A and B (if applicable), on behalf of the Disclosing Party, and (2) warrants that all certifications and statements contained in this EDS, and Appendices A and B (if applicable), are true, accurate and complete as of the date furnished to the City. Submission of this form constitutes making the oath associated with notarization.

/s/ 03/30/2020

Dr. Ari Michael Levy

President

Shift Medical, Ltd.

This is a printed copy of the Economic Disclosure Statement, the original of which is filed electronically with the City of Chicago. Any alterations must be made electronically, alterations on this printed copy are void and of no effect.

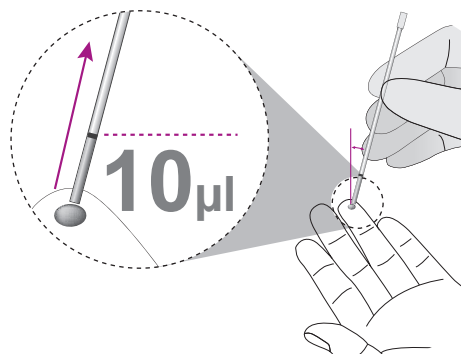
TEST PROCEDURE - Be sure to test both STANDARD Q COVID-19 IgM and IgG simultaneously.

The test procedures for both COVID-19 IgM and IgG are the same.

Using Capillary whole blood

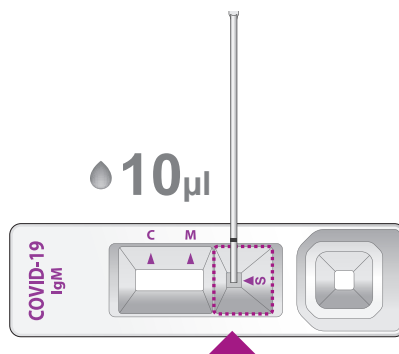
1 Collecting of Specimen

Using a capillary tube, collect the 10 μ l of capillary whole blood to the black line of the capillary tube.



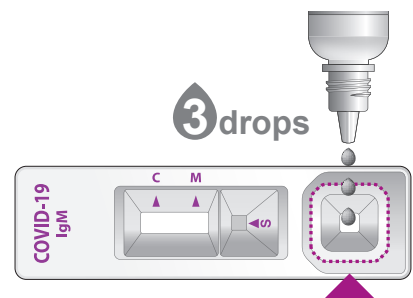
2 Adding of Specimen

Add the collected capillary whole blood to the specimen well of the test device.



3 Dropping of buffer

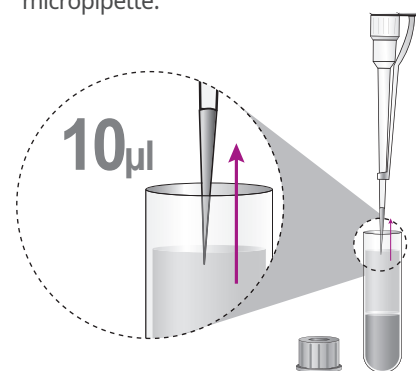
Add 3 drops (90 μ l) of buffer vertically to the buffer well of the test device.



Using serum/plasma/venous whole blood

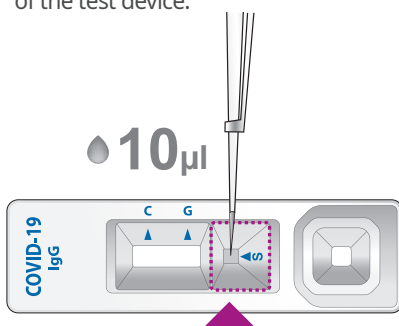
1 Collecting of Specimen

Using a micropipette, collect the 10 μ l of serum, plasma or venous whole blood with micropipette.



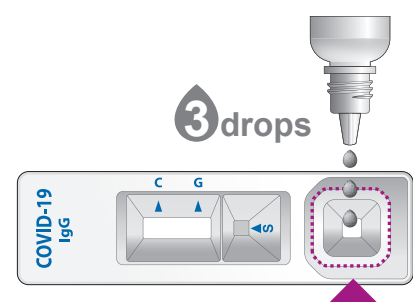
2 Adding of Specimen

Add the collected serum, plasma or venous whole blood to the specimen well of the test device.



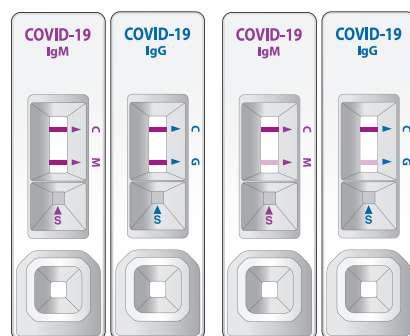
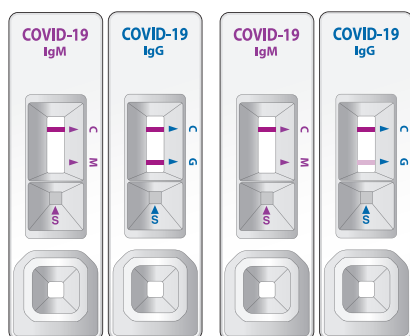
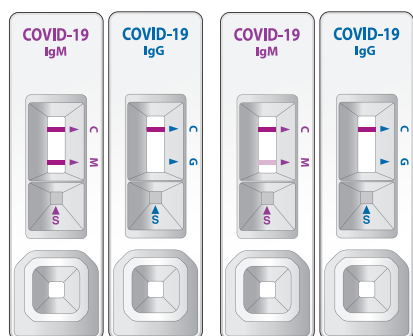
3 Dropping of buffer

Add 3 drops (90 μ l) of buffer vertically to the buffer well of the test device.

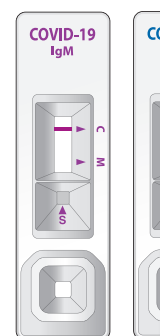


INTERPRETATION OF TEST RESULT

Positive



Negative



1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C).
2. A colored band will appear in the lower section of the result window. These bands are test line of IgM/IgG (M, G).

3. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted.

* **STANDARD Q COVID-19 IgM/IgG Duo Test may cross-react with antibody against SARS-Corona-1.**

* **Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.**

* **Positive results should be considered in conjunction with the clinical history, RT-PCR results and other data available.**

- Do not use the buffer or another lot.
- Do not smoke, drink or eat while handling specimen.
- Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
- Clean up spills thoroughly using an appropriate disinfectant.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
- Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating desiccant beads change from yellow to green, the test device in the pouch should be discarded.
- Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

- Collect the whole blood into the commercially available plain tube, NOT containing anti-coagulants such as heparin, EDTA, Sodium citrate by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- If serum in the plain tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -40°C/-40°F.
- They should be brought to room temperature prior to use.

[Plasma]

- Collect the venous blood into the commercially available anti-coagulant tube such as heparin, EDTA, Sodium citrate by venipuncture and centrifuge blood to get plasma specimen.
- If plasma in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -40°C/-40°F.
- They should be brought to room temperature prior to use.

[Whole blood]

• Capillary whole blood

- Capillary whole blood should be collected aseptically by fingertip.
- Clean the area to be lanced with an alcohol swab.
- Squeeze the end of the fingertip and pierce with a sterile lancet.
- Using a capillary tube, collect the 10µl of capillary whole blood to the black line of the capillary tube.
- The capillary whole blood must be tested immediately after collection.

• Venous whole blood

- Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, EDTA, Sodium citrate by venipuncture.
- If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1-2 days after collection.
- Do not use hemolyzed blood Specimens.



CAUTION

- As known relevant interference, hemolytic Specimen, rheumatoid factors-contained Specimen and lipemic, icteric Specimen can lead to impair the test results.
- Use separate disposable materials for each Specimen in order to avoid cross-contamination which can cause erroneous results.

PERFORMANCE CHARACTERISTICS

[Clinical evaluation]

Test were performed according to instructions for use of 'STANDARD Q COVID-19 IgM/IgG Duo Test' with residual serum from 33 positive patients confirmed by real-time PCR (2019-nCoV Real-time PCR kit) method and 30 healthy donors.

• Positive specimens

No.	Onset of Symptom date	Confirmation Test date	Blood collection date	Days after symptom onset	STANDARD Q COVID-19 IgM/IgG Duo Test result	
					IgM	IgG
1	Unknown	Feb. 09, 2020	Feb. 17, 2020	Unknown	Positive	Pos weak
2	Unknown	Jan. 30, 2020	Feb. 17, 2020	Unknown	Positive	Positive
3	Unknown	Feb. 02, 2020	Feb. 17, 2020	Unknown	Positive	Positive
4	Feb. 15, 2020	Feb. 23, 2020	Feb. 23, 2020	8	Pos weak	Pos weak
5	Feb. 15, 2020	Feb. 23, 2020	Feb. 27, 2020	12	Pos weak	Positive
6	Feb. 15, 2020	Feb. 23, 2020	Mar. 03, 2020	17	Pos weak	Positive
7	Feb. 06, 2020	Feb. 09, 2020	Feb. 13, 2020	7	Negative	Negative
8	Feb. 06, 2020	Feb. 09, 2020	Feb. 21, 2020	15	Pos weak	Positive
9	Feb. 06, 2020	Feb. 09, 2020	Mar. 03, 2020	26	Pos weak	Positive
10	Feb. 18, 2020	Feb. 19, 2020	Feb. 19, 2020	1	Negative	Negative
11	Feb. 18, 2020	Feb. 19, 2020	Feb. 26, 2020	8	Negative	Positive
12	Feb. 19, 2020	Feb. 19, 2020	Feb. 23, 2020	4	Negative	Negative
13	Feb. 15, 2020	Feb. 23, 2020	Feb. 23, 2020	8	Positive	Positive
14	Feb. 6, 2020	Feb. 9, 2020	Mar. 03, 2020	26	Positive	Positive
15	Jan. 30, 2020	Feb. 1, 2020	Feb. 09, 2020	10	Negative	Negative
16	Jan. 25, 2020	Feb. 1, 2020	Feb. 12, 2020	18	Positive	Positive
17	Feb. 25, 2020	Feb. 25, 2020	Mar. 03, 2020	7	Negative	Positive
18	Feb. 15, 2020	Feb. 23, 2020	Feb. 25, 2020	10	Positive	Positive
19	Feb. 6, 2020	Feb. 9, 2020	Feb. 21, 2020	15	Positive	Positive
20	Jan. 30, 2020	Feb. 1, 2020	Feb. 13, 2020	14	Positive	Positive
21	Jan. 25, 2020	Feb. 1, 2020	Feb. 09, 2020	15	Trace	Positive
22	Feb. 15, 2020	Feb. 23, 2020	Feb. 26, 2020	11	Positive	Positive
23	Feb. 6, 2020	Feb. 9, 2020	Feb. 17, 2020	11	Positive	Positive
24	Jan. 30, 2020	Feb. 1, 2020	Feb. 06, 2020	7	Negative	Negative
25	Feb. 18, 2020	Feb. 21, 2020	Feb. 26, 2020	8	Negative	Negative
26	Feb. 15, 2020	Feb. 23, 2020	Feb. 27, 2020	12	Positive	Positive
27	Feb. 6, 2020	Feb. 9, 2020	Mar. 01, 2020	24	Positive	Positive
28	Jan. 25, 2020	Feb. 1, 2020	Feb. 17, 2020	23	Positive	Positive
29	Feb. 25, 2020	Feb. 25, 2020	Mar. 02, 2020	6	Negative	Positive
30	Feb. 15, 2020	Feb. 23, 2020	Feb. 29, 2020	14	Positive	Positive
31	Feb. 22, 2020	Feb. 24, 2020	Mar. 06, 2020	13	Negative	Positive
32	Feb. 4, 2020	Feb. 4, 2020	Feb. 20, 2020	16	Negative	Positive
33	Feb. 4, 2020	Feb. 4, 2020	Feb. 20, 2020	16	Negative	Positive

		PCR	
		Positive	Negative
STANDARD Q COVID-19 IgM+IgG	Positive	25	1
	Negative	2	29
Total		27	30
Sensitivity : 92.6%, Specificity : 96.6%			

- Based on result of test with positive specimens, it was found that COVID-19 from the time when after about 7 days from the date of onset with negative specimens.

ANALYTICAL PERFORMANCE

- Limit of Detection:** IgM-0.02 mg/ml, IgG-0.02 mg/ml
- Cross-Reactivity:** No cross-reactivity for HIV positive plasma, Japanese positive plasma, Salmonella typhi IgM positive plasma, Rubella IgM, C. palladium, HAV IgM positive plasma, HAV IgG positive plasma, HBV positive plasma, Brucella IgM positive plasma, Chagas positive plasma, Toxoplasma, Synephrine, Afrin Nasal Spray, Saline Nasal Spray), Homeopathic all, Hydrochloride), Anti-viral drugs (Zanamivir, Oseltamivir, Artemether, medication (Acetaminophen, Acetylsalicylic acid, Ibuprofen), Antibiotic. Elevated levels of C-reactive protein for IgM and IgG
- Interference study:** No Interference for Respiratory Specimens (Mucosynephrine, Afrin Nasal Spray, Saline Nasal Spray), Homeopathic all, Hydrochloride), Anti-viral drugs (Zanamivir, Oseltamivir, Artemether, medication (Acetaminophen, Acetylsalicylic acid, Ibuprofen), Antibiotic. Elevated levels of C-reactive protein for IgM and IgG
- High-dose Hook Effect:** No hook effect at the concentration of 1.25 mg/ml
- Matrix Equivalency:** The difference of Matrix (Capillary whole blood, Venous whole blood, Serum)

Sort	Matrix	A
COVID-19 IgG antibody spiked	Serum	N
	Plasma	H
	Plasma	E
	Venous whole blood	S
	Venous whole blood	E
COVID-19 IgG antibody spiked	Capillary whole blood	S
	Serum	E
	Plasma	N
	Plasma	E
	Venous whole blood	S
N/A	Capillary whole blood	H
	Serum	S
	Plasma	H
	Plasma	E
	Venous whole blood	S
N/A	Capillary whole blood	E
	Serum	N
	Plasma	H
	Plasma	E
	Venous whole blood	S

- Stability schedule for 24months of claimed shelf life**
 - Accelerated Aging Test: February, 2020 ~ August, 2020 (for 19 weeks)
 - Real time stability Test: February, 2020 ~ May, 2022 (for 26 months)

LIMITATION OF TEST

- The test procedure, precautions and interpretation of results for this test.
- This test detects the presence of SARS-CoV-2 IgM/IgG in the specimen.
- Test results must be considered with other clinical data available to the patient.
- For more accuracy of immune status, additional follow-up testing using other methods is recommended.
- Neither the quantitative value nor the rate anti-SARS-CoV-2 IgM/IgG can be used for diagnosis.
- Failure to follow the test procedure and interpretation of test results may lead to incorrect results.

NOTIFICATION FOR COVID-19

- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those with symptoms considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to confirm or rule out infection.
- Positive results may be due to past or present infection with non-SARS-CoV-2 virus (no. 6).
- Not for the screening of donated blood.
- The test procedure should be conducted in ambient temperature and humidity.
- Results of these tests should be appropriately recorded in a test report.

BIBLIOGRAPHY

- Clinical management of severe acute respiratory infection when novel coronavirus (2019-nCoV) is identified.
- Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR.
- Diagnosis and treatment of pneumonia caused by new coronavirus (2019-nCoV).



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Any inquiries regarding in



Reference number



In vitro Diagnostics



Consult Instructions for Use



Contains Sufficient for <n> Tests



Caution



Observe the temperature limitations in which the transport package has to be kept and handled.



Note



Do not re-use.



Use by



Batch code



Manufacturer



Date of manufacture